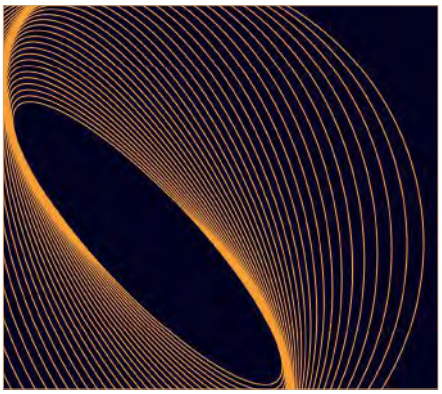

Customized Treatment Using Microfocused Ultrasound with Visualization for Optimized Patient Outcomes: A Review of Skin-tightening Energy Technologies and a Pan-Asian Adaptation of the Expert Panel's Gold Standard Consensus

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ABSTRACT

BACKGROUND: Noninvasive facial-rejuvenation devices, such as nonablative radiofrequency (RF) and laser-assisted technology, are increasingly replacing higher-risk surgeries for face and body skin laxity. **OBJECTIVE:** We sought to review published information on noninvasive energy device safety and efficacy in aesthetic skin tightening, compare these with our experiences in Asian patients, and disseminate a consensus for optimizing microfocused ultrasound with visualization (MFU-V) in Asian patients. **METHODS:** A broad, nonexhaustive, nonsystematic literature search of published studies indexed in PubMed was performed to compare selected energy technologies to MFU-V for noninvasive face and body skin tightening, in particular, among Asian patients. This was supplemented with internal documents to provide evidence and support arguments if no peer-reviewed data were available. **RESULTS:** We highlighted the differences between devices and platforms and identified factors requiring attention and caution. Due to the increase in new devices lacking strong supporting clinical evidence of both safety and efficacy in Asia, it is necessary to convene physicians with substantial experience in MFU-V and devise a consensus on Asian patient selection, treatment planning, and customization. **CONCLUSION:** Many platforms duplicate or claim similar technologies, efficacy, or safety without significant peer-reviewed scientific or clinical evidence. We showed that MFU-V satisfies this clinical imperative. Further, the patented DeepSEE® technology allows users to noninvasively "see" through the skin to ensure treatment precision, facilitate optimal skin lifting and tightening, and enhance patient comfort and safety. Therefore, we believe that MFU-V is the gold standard for nonsurgical lifting and skin tightening.

KEY WORDS: Nonsurgical skin tightening, energy device, MFU-V, HIFU, Asian

Face and body skin laxity cannot be improved with diet and exercise alone.[1] The International Association for Physicians in Aesthetic Medicine recently noted that noninvasive facial-rejuvenation devices, such as nonablative radiofrequency (RF) and laser-assisted technology, are increasingly replacing higher-risk surgeries for these problems.[2]

Monopolar RF and intense focused ultrasound (IFU) are noninvasive, energy-based technologies for facial lifting, tightening, and contouring. IFU devices use transducers to concentrate variable acoustic or ultrasound energy within a small, targeted, subcutaneous tissue area, such as the superficial musculoaponeurotic system (SMAS).[3] The target tissue is heated to more than 65°C, denaturing proteins in the area almost immediately, leading to the contraction of collagen fibers[4] and stimulating *de-novo* neocollagenesis that lifts and tightens skin. IFU devices include those using high-intensity focused ultrasound (HIFU) or microfocused ultrasound with visualization (MFU-V). Ultherapy® (Merz North America, Inc., Raleigh, North Carolina), also known as MFU-V, is cleared by the United States (US) Food and Drug Administration (FDA) for the noninvasive lifting of the brow,[5,6] neck, and submentum,[6] and for relieving décolleté wrinkles and lines.[7] Meanwhile, the European Union has cleared MFU-V for upper and lower face, neck, and décolleté contouring and lifting.[8] None of the available IFU devices are as robustly supported by clinical evidence as MFU-V, making MFU-V the current gold standard for noninvasive skin lifting.[43] MFU-V delivers low-

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energy MFU (0.4–1.2 J/mm^2) to three different depths—1.5mm, 3.0mm, and 4.5mm—to heat target tissues from superficial skin to SMAS.[5] This heat creates 1-mm^3, inverted cone-shaped microthermal lesions down to the 5-mm-deep reticular layer of the dermis and subdermis without harming the overlying papillary dermal and subdermal layers.[9] MFU-V can therefore be used to tighten and lift the SMAS and treat wrinkles or sagging skin in the face, neck, and décolleté.[10] One distinctive feature of MFU-V is its capacity for real-time visualization up to 8.0mm, which HIFU lacks.[3,8] While HIFU and RF systems rely on the somewhat blind application of energy, MFU-V incorporates a real-time, high-resolution ultrasound imager, which lets users simultaneously "see and treat" distinct tissue layers, including the SMAS, subcutaneous fat, dermis, and epidermis. Table 1 summarizes the differences between HIFU and MFU-V.

In Asia, popular monopolar RF technologies include the Thermage (Comfort Pulse Technology, Solta Medical Hayward, California), ThermiTight (ThermiAesthetics, Southlake, Texas), and TruSculpt (Cutera, Inc., Brisbane, California) systems. All energy devices[11–14] are associated with some adverse events, such as poor RF technique leading to blistering and crusting.[15,16] When emitted RF heat energy traveling through tissue is impeded by adipocytes, it localizes within the obstructing cells and thermolyzes them[1] but can also induce dermal regeneration through neocollagenesis and elastogenesis, producing skin tightening.[17]

Ulthera's DeepSEE® technology works in dual stages, with an immediate tissue-lifting effect followed by a wound-healing response. First, MFU energy is concentrated in dermal and subcutaneous tissues, causing collagen fibrils within them to heat to 60°C to 70°C, creating focal points of thermal injury known as thermal coagulation points (TCPs).[9,18,19] These temperatures are optimal for the collagen fibril contraction and denaturation that produces the initial lift. Wound healing in the second stage induces neocollagenesis for tissue remodeling. From 48 hours until 10 weeks after treatment,[20] inflammation also stimulates neocollagenesis, fibroblast proliferation, and elastogenesis around the TCPs. By Day 28, the adjacent dermis undergoes remodeling and viscoelasticity increases. Over time, the tissue lifts and the skin thickens and tightens, further increasing elastin in the injury zone and collagen in the reticular dermis.[21] Ten weeks after treatment, neocollagenesis[22] completely replaces the existing collagen in treated areas with thermal injury,[20] further tightening and lifting the skin in a sustained remodeling phase that can last for up to one year. The availability of six MFU-V transducers allows customization to three different tissue depths—4.5mm, 3.0mm and 1.5mm—below the skin. Narrow transducers (10 MHz/1.5 mm and 7.0 MHz/3.0 mm) are also available for smaller areas and can be used alongside the wider transducers. Individual variations in tissue thickness can be visualized through MFU-V and, with the availability of transducers targeting different depths, physicians can now customize treatments based on skin thickness. MFU-V can be used at more than one tissue depth per treatment session, and multiple studies show that both single- and dual-depth treatments improve, tighten, or regenerate sagging skin on the face, neck,[5,23–30] abdomen,[31] knees,[31,32] upper arms,[31] thighs,[31] buttocks,[33] and elbows.[34]

TABLE 1. Comparison of Ulthera and high-intensity focused ultrasound (HIFU) technologies; courtesy of JY Park

	ULTHERA	HIFU
Depth	Exact focusing	Variable quantity and inconsistent placement of energy
TCP volume	Constant, uniform	Variable size and placement of TCPs can lead to TCP coalescence
TCP spacing	Precise and consistent spacing of 1.0–1.5mm	Variable and inconsistent spacing between TCPs
Visualization	Real-time visualization with patented technology	Not real-time ultrasound visualization
Safety	Proven safety profile	Insufficient evidence
Clinical data	>50 clinical studies and >90 peer-reviewed papers	Few peer-reviewed publications
Protocol	Usually used once yearly with longer treatment intervals, indicating longer-lasting effects	Usually used 3–4 times a year, indicating shorter treatment intervals and shorter periods of efficacy
Approval	The only US FDA-cleared, noninvasive lifting device	Not cleared for sale in the United States

TCP: thermal coagulation point; USFDA: United States Food and Drug Administration

A GOLD-STANDARD DEVICE WITH REAL-WORLD EVIDENCE IN CLINICAL PRACTICE

The MFU-V device includes real-time ultrasound imaging that targets specific tissue layers and avoids critical structures, such as bone and blood vessels. By merely adjusting standardized algorithms and optimizing MFU energy levels and line densities, tissues in multiple planes can be lifted and tightened. In one author's practice, prioritizing comfort and satisfaction led to 60 percent of patients returning for repeat treatments.[35] Recent publications and consensus guidelines have also made recommendations supporting the tailoring of MFU-V treatments to each patient. For example, the "See-Plan-Treat" tool visualizes tissue planes and anatomies before a personalized, tissue-targeting strategy for MFU delivery is devised. The tool was found to improve treatment comfort, efficacy, and success.[36]

A range of MFU-V transducers is available to target MFU to the different tissue depths of the SMAS/fibrous and dermal layers,[30] with dual-depth treatments found to produce superior outcomes.[27] For dual-depth treatments, the manufacturer recommends targeting the superficial fascial/SMAS and deep dermal layers. A significant brow lift was achieved in 86 percent of patients 90 days after MFU-V was applied to the whole face and neck at 4.5mm and 3.0mm.[37] In the submentum, almost 73 percent of patients had visible submental lift of greater than 20.0mm^2, which persisted in nearly 69 percent of subjects at three months.[28] We observed skin laxity improvements in almost 78 percent of patients receiving face and neck MFU treatments, with results persisting in 67 percent of patients 180 days later.[38] After 90 days, MFU-V also significantly improved the décolleté in 46 percent of patients with moderate-to-severe rhytids, and 62 percent of these patients showed sustained improvement at 180 days.[39] Of patients receiving multiple MFU-V passes during dual-depth treatments, 58.1 percent also had

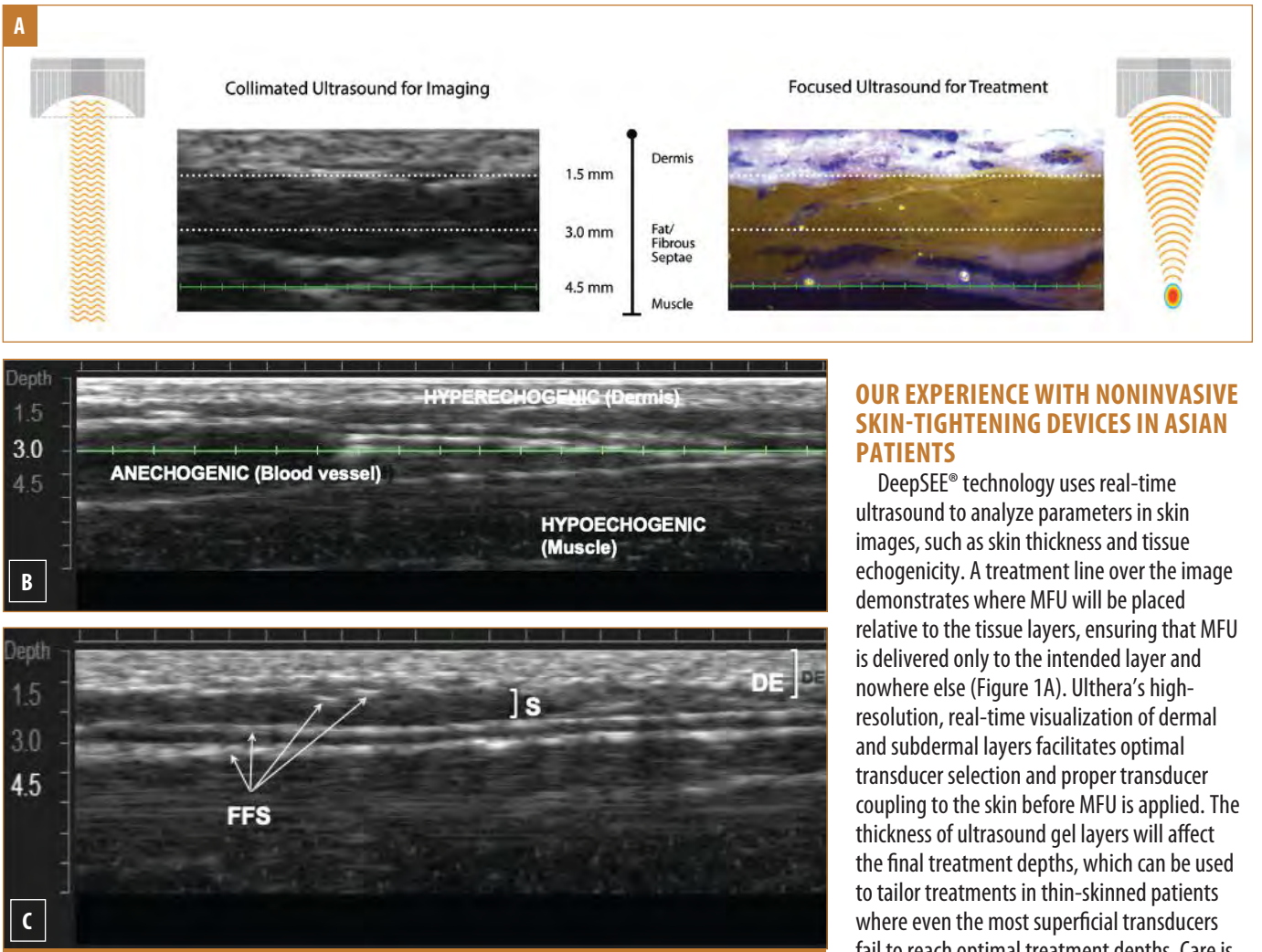

FIGURE 1A–C. Ultrasound imaging of the skin. A) Ulthera® DeepSee® imaging allows precise visualization of tissue layer(s). B) Regions with differing degrees of echogenicity are shown. Ultrasound waves are scattered well by hyperechogenic regions, resulting in bright image areas, such as those seen in the dermis. Hypoechogenic regions reflect or scatter ultrasound waves poorly, resulting in dim image areas, such as those seen in the muscle. Anechogenic regions neither reflect nor scatter ultrasound waves, resulting in dark areas, such as those seen in blood vessels. C) Ultrasound image of the skin layers.
Abbreviations: DE: dermis; FFS: fascia, fibrous septae; *S*: subcutaneous fat

improved cheek and submental skin laxity and jawline definition at 90 days posttreatment, with improved lower face and neck in 65.6 percent of patients.[28] MFU-V results are long-lasting, as shown by the relief of marionette folds[40] and improved lower face and neck skin laxity at one[38,41] and even two years[42] posttreatment.

By applying our gold-standard consensus recommendations[43] of using the highest tolerable MFU energy setting, but reducing this according to patient comfort while maintaining the necessary density of treatment lines, patients only experience mild discomfort. A split-face study on marionette lines found that using higher MFU energies (in other words, delivering greater line densities or using higher energy levels) and more treatment planes (or two or three tissue depths) led to more significant tissue lifting and elasticity.[38] Treating just a single depth is unlikely to give the ideal TCP density for effective treatments and may cause stacking of TCPs, thus leading to adverse events. Table 2 demonstrates that variations in protocol facilitate treatment success when physicians use MFU-V with a good understanding of facial anatomy and Ulthera technology and understand how to optimize outcomes.[43]

OUR EXPERIENCE WITH NONINVASIVE SKIN-TIGHTENING DEVICES IN ASIAN PATIENTS

DeepSEE® technology uses real-time ultrasound to analyze parameters in skin images, such as skin thickness and tissue echogenicity. A treatment line over the image demonstrates where MFU will be placed relative to the tissue layers, ensuring that MFU is delivered only to the intended layer and nowhere else (Figure 1A). Ulthera's high-resolution, real-time visualization of dermal and subdermal layers facilitates optimal transducer selection and proper transducer coupling to the skin before MFU is applied. The thickness of ultrasound gel layers will affect the final treatment depths, which can be used to tailor treatments in thin-skinned patients where even the most superficial transducers fail to reach optimal treatment depths. Care is necessary to avoid treating too superficially, however, as burns can occur.[44,45] This highlights the importance of being able to make fine adjustments to gel layer thickness so that MFU can be placed either slightly above or below the set transducer depth.[25] It also underscores the necessity of visualizing tissue depths.[46] Moreover, Asian patients, who have denser SMAS, deep fascia connections, and thinner skins with lipid-rich stratum corneum,[46] will benefit from tissue visualization, as this increases the accuracy of MFU placement.

In Asian patients, MFU-V outcomes can be affected by the different protocols available. Lee et al[30] used 4-MHz/4.5-mm and 7-MHz/3.0-mm transducers to deliver an average of 238 lines in the dermal and fibrous layers of the lower face and neck, resulting in improvements for 90 percent of patients at 90 days posttreatment. Jung et al[47] used a 4-MHz/4.5-mm transducer on Korean patients to deliver 100 to 120 lines

for facial tightening. Thus, even with variable line numbers and transducer strengths, MFU-V consistently produces successful outcomes (summarized in Table 2 for selected anatomical sites). MFU-V offers an unrivaled level of precision by leveraging the variable echogenicity (i.e., the ability to reflect or scatter ultrasound waves) of the different tissue layers (Figures 1B–1F). Under ultrasound, the dermis and epidermis display homogenously bright areas.[48,49] Normal, collagen-rich fascia appears as continuous, bright, and linear structures bordering fat and muscle. Subcutaneous fat creates bands with varying thickness, whereas fibrous septae appear as short, curvilinear, bright lines or specks. The thinner upper dermis can be distinguished from the lower dermis on ultrasound as it has fewer collagen fibers. The thin papillary dermis layer only weakly reflects ultrasound and thus echoes less than thicker, collagen-rich, lower dermis tissues. As such, the upper papillary layer can be differentiated from the lower reticular dermis layer on ultrasound. Blood vessels do not reflect ultrasound waves and appear as dark areas. Figure 2 illustrates the variations in subdermal anatomies for four Asian patients receiving MFU-V in equivalent anatomical areas. Physicians can leverage this information to accurately diagnose patients and target MFU.

There are few peer-reviewed publications on the efficacy and safety of alternative HIFU devices, including Korean devices such as the Ultraformer® III (Classys Inc., Seoul, Korea), Ultraskin™ (WONTECH Co., Daejeon, Korea), and Doublo™ (HIRONIC Co., Sungnam, Korea).[21,50–52] While MFU-V has been *de-novo* cleared by the US FDA for noninvasive lifting since 2009, Ultraformer III has been approved by the Korean FDA since 2012, but lacks US FDA clearance. There is no published evidence to support the manufacturer's claims that Ultraformer III creates skin coagulation points within target tissue layers at approximately 65.4°C,[53] contrasting starkly with MFU-V's peer-reviewed data showing its consistent heating of tissue to 60° to 70°C.[54,55] Moreover, MFU-V's thermal coagulation points are precisely spaced and consistently placed at specific depths without surface disruption; there is no information for how or if this occurs with the Ultraformer III. Clinical data on the efficacy and safety of the Ultraformer III device are also limited, with only one published clinical trial for the face, another for both the face and body, and a third on a pilot study for the body.[28,38,56–59]

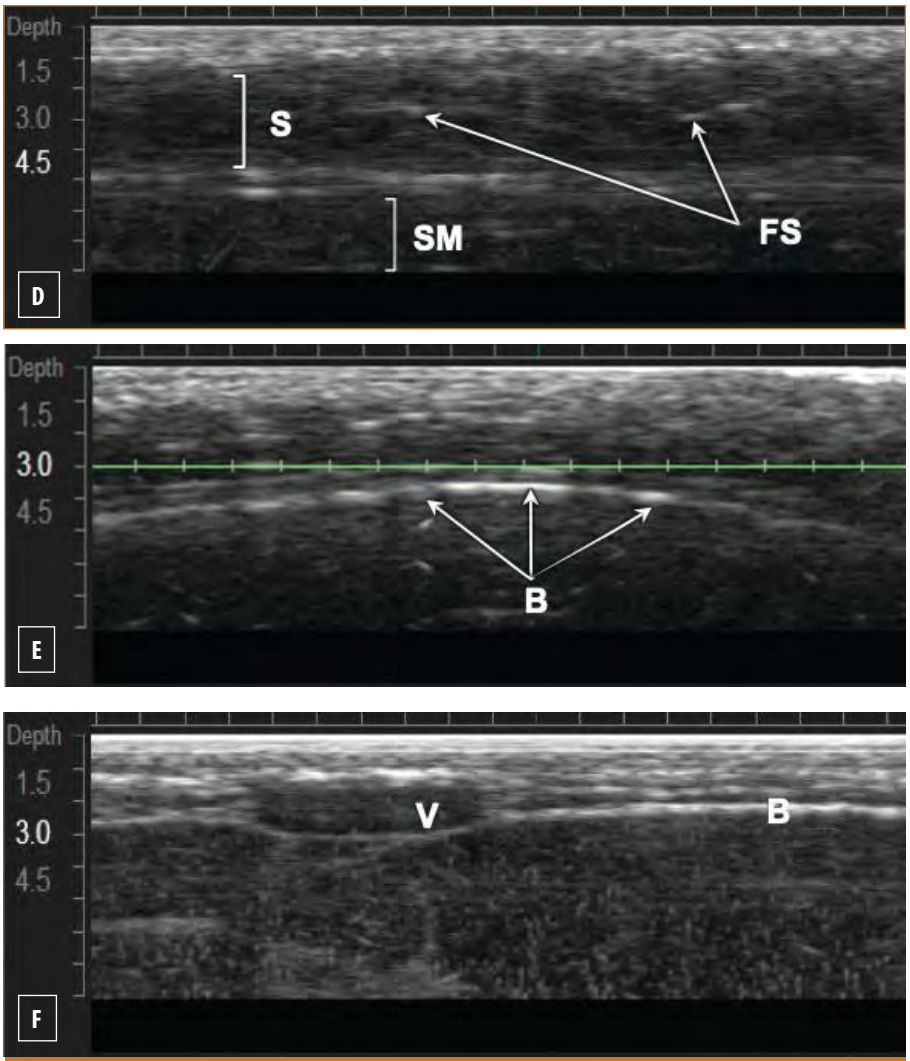

FIGURE 1D–F. Ultrasound imaging of the skin. D–F) Skin structures have various echogenicities: the muscle is hyperechogenic; bone has well-defined, linear, smooth, and continuous hyperechogenic lines; and blood vessels can be either hypoechogenic or anechogenic.
Abbreviations: S: subcutaneous fat; FS: fibrous septae; SM: skeletal muscle; B: bone; V: vessel

The Doublo system has three transducers with energy levels that claim to target either the upper dermis, deep dermis, or SMAS. In contrast, MFU-V's six transducers target three tissue depths (4.5, 3.0, and 1.5mm) and offer adjustable energy levels. One Doublo study found it to be less effective for noninvasive skin tightening and skin rejuvenation than another study,[60] and attributed this inconsistency to the use of different Doublo devices. Such limited data and erratic practices force physicians to make decisions based on unreliable scientific evidence. We observed unintended outcomes following HIFU in a 56-year-old female patient, who underwent two HIFU (device name and model unknown) treatments over a three-month period before presenting to the author's clinic after six months (Figure 3A–B). She developed tear trough bulging, tear trough aggravation, sunken cheeks, and increased skin laxity, all of which were caused by excessive and uncontrolled delivery of HIFU to the superficial or deep fat layers. A second, 35-year-old female patient also developed adverse effects five months after receiving 400 lines of HIFU (Figure 3C–D) and presented to the author's clinic with skin laxity and crepiness, tear trough aggravation, sunken cheeks, and periorbital and perioral fine lines. We also caution that these cases represent only the milder consequences of

TABLE 2. Summary of MFU lines and transducers used in selected studies

AREA	TREATMENT GOAL	TRANSDUCER PARAMETERS	RESULTS	CITATION
Supra-brow area, lateral canthus, and the infraorbital area	Ptosis	Per face side, above lateral eyebrow: First pass: 7 MHz/3.0 mm, 15 lines Second pass: 10 MHz/1.5mm Per face side, lateral eye and infraorbital area bilaterally: 7 MHz/3.0mm, 10 lines 10 MHz/1.5mm, 10 lines	Combination with fillers injected into sunken upper eyelid, lateral eyebrow and the infraorbital area increased eyebrow height by 3.5mm; maximum height was 3.9mm at Week 12	Park et al[70]
Full face or neck	Skin tightening	First pass: 4 MHz/4.5mm Second pass: 7 MHz/3.0mm Total: 600–700 lines	Lifting and tightening of facial and neck tissue improved subject and physician Global Aesthetic Improvement Scale to 90% and 100% at 90 and 180 days, respectively, and 95% for both measures at one year. At one year, 79% reported less sagging, 58% reported fewer wrinkles, and 47% reported smoother skin texture.	Werschler et al[41]
Décolletage	Skin tightening and rhytids	First pass: 4.0 MHz/4.5mm; 120 lines Second pass: 7.0 MHz/3.0mm; 120 lines	Rhytids were evaluated using the validated Fabi/Bolton Chest Wrinkle Scale (FBCWS) and 46% of subjects had a FBCWS score of 1 or 2 points at Day 90, while 62% had a score of 1 or 2 points by Day 180. Mid-clavicular to nipple distance was decreased at Days 90 and 180. At Day 90, 100% of cases were improved per Subject GAIS and 96% were improved per Physician GAIS, with similar findings at Day 180. All subjects reported being satisfied or very satisfied at Day 90, with similar results at Day 180.	Fabi et al[39]
Knee	Skin tightening and sagging	Single pass: 4 MHz/4.5mm; 20 lines per 25 x 25-mm square	86% of patients showed improved lifting and tightening of knee skin laxity at 90 and 180 days	Gold et al[32]
Lower face and submentum	Skin tightening and sagging	First pass: 4 MHz/4.5mm Second pass: 7 MHz/3.0mm Neck: total 50 lines Cheek lower: total 55 lines per side Neck: total 50 lines per side Cheek medial: total 40 lines per side	At Day 90, 65.6% of patients perceived improvement in skin laxity	Kenkel[28]
Lower face and neck	Skin tightening	First pass: 4 MHz/4.5mm Second pass: 7 MHz/3.0mm Average: 238 lines	80% of subjects showed clinical improvement at 90 days; 90% reported subjective improvement	Lee et al[30]

suboptimal HIFU treatment.

In contrast, the safety and efficacy of MFU-V is supported by more than 50 clinical studies and 90 peer-reviewed publications, both independent and company-sponsored, with patients of various ethnic groups, sexes, ages, and follow-up durations. Additionally, more than 1.5 million treatments with MFU-V have been performed globally (as of June 2019).[61] Our recent consensus highlighted MFU-V's high precision at TCP formation and targeting specific tissue depths and its demonstrated safety profile.[43] While we found that 800 to 1,200 lines were optimal for full-face and neck treatments, we also stressed that this should be customized to patient needs, face size, skin laxity, fat distribution, skin quality, and ultrasound image results. Ultrasound imaging should be performed to estimate SMAS depths relative to superficial skin depths and for the correct transducers and number of lines for each tissue plane to be determined.

Users should be wary of the entry of cheaper, copycat, and counterfeit devices from East Asia into clinics worldwide.[62] Many of these devices lack system feedbacks, fail-safes, or manufacturer assurances of safety, reliability, or reproducibility. Most have not undergone comprehensive, long-term testing in multiple clinical trials for safety and efficacy.[63] Copycat devices can cause serious adverse events. For example, copycat cryolipolysis systems have caused burns and freeze injuries[63] while some HIFU systems have caused corneal stromal damage.[64] Without the exacting and rigorous standards of clinical studies, it is difficult to establish clear guidance to prevent improper techniques or untested protocols.

PERSONALIZATION IS IMPORTANT

Deep tissue visualization is important for precision, consistency, and safety of aesthetic treatments. Ulthera DeepSEE® ultrasound imaging enables physicians to see, in real-time, the target tissue layer. No other FDA-cleared, nonsurgical energy device has this visualization capability. As inaccurate energy delivery can be detrimental, users must correctly identify the SMAS or superficial fascia layers, whose depths can differ depending on patient weight, body mass index, age, sex, and target area.[65,66]

Though research is needed to confirm our observations, in the authors' clinical experience, the efficacy of the results are determined by the quality of energy delivered, which is also affected by depth, temperature, volume, and precision. Per their clinical experience, skin burns, scars, and longer recovery times can result from the delivery of too much ultrasound energy and, thus, high temperatures, or from the creation of excessively large or inconsistently spaced TCPs. Burns can also result from ultrasound energy delivered at too-shallow depths. Poor coupling of the transducer to skin or stacking of energy pulses can also cause burns. Treatment efficacy is affected by low energy and temperature levels,

targeted tissue depths being too deep and affecting bone, or failure to create TCP due to imprecise delivery. These factors all affect the optimum temperature required for collagen denaturation and subsequent neocollagenesis. Also, TCPs that are too small can only treat low volumes of tissue, thus reducing efficacy. These observations require additional research before firm conclusions can be made.

Synergistic combinations of multiple aesthetic modalities enhance the efficacies of individual ones, and multimodality approaches incorporating MFU-V are recommended in position statements, consensus documents, clinical studies, and trials.[67–71] MFU-V augments the effects of neuromodulators, biostimulators, and fillers, and can achieve natural results when used judiciously to avoid overtreatment.[67] MFU-V can tighten and strengthen an area of skin before fillers are placed there, while also enhancing their volumization or collagen-stimulating effects, such as during cellulite or atrophic acne scarring treatments.[71–75] Delivery of MFU energy over areas injected with hyaluronic acid and calcium hydroxylapatite (CaHA) fillers does not change filler appearances, increase inflammation, or induce product migration but can increase collagen fiber density and thickness.[74,76] The upper face can be treated first with MFU-V to tighten skin and lift ptotic brows, followed by botulinum toxin A (BoNT/A) to relax brow depressor muscles, and fillers to correct temporal hollowing and forehead contours.[68] Because MFU-V's dual-phase mechanism of action delays neocollagenesis so that tissue lifting occurs later, this combination approach improves eyebrow heights, eyebrow ptosis, infraorbital hollows, and superior sulcus deformities, even at 12 weeks posttreatment.[70] In the midface, fillers can reinflate fat pads and address depleted cheek volume and lost bony support, while MFU-V can lift and tighten the zygomatic-buccal retaining ligaments. Combining different modalities also effectively improves the nasolabial folds, melolabial fold, and jawline. Further, MFU-V improves ultraviolet B-induced pigmentation, which might be an adjunct benefit and new indication for facial rejuvenation.[79]

In August 2019, expert dermatologists and plastic surgeons from the Asia-Pacific region convened in Kuala Lumpur, Malaysia, to discuss and come to a consensus regarding

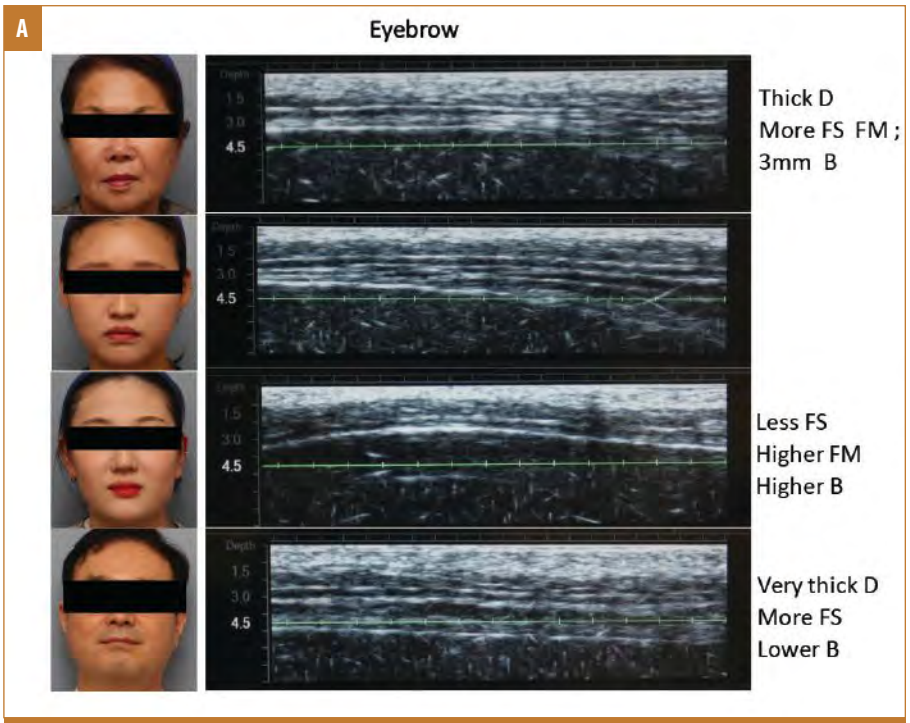

FIGURE 2A. Individual Variability in Asians; different Asian patients receiving MFU-V for A) eyebrow, B) submentum, and C) lower neck skin laxity display different subdermal anatomies. Age of patients, from top to bottom: 58 years, 34 years, 32 years, and 48 years.
FM: frontalis muscle; D: dermis; FS: fibrous septae; SM: skeletal muscle; S: subcutaneous fat; B: bone; V: vessel. Image courtesy of Dr. Je-Young Park. Informed and written patient consents were obtained for the use of patient images.

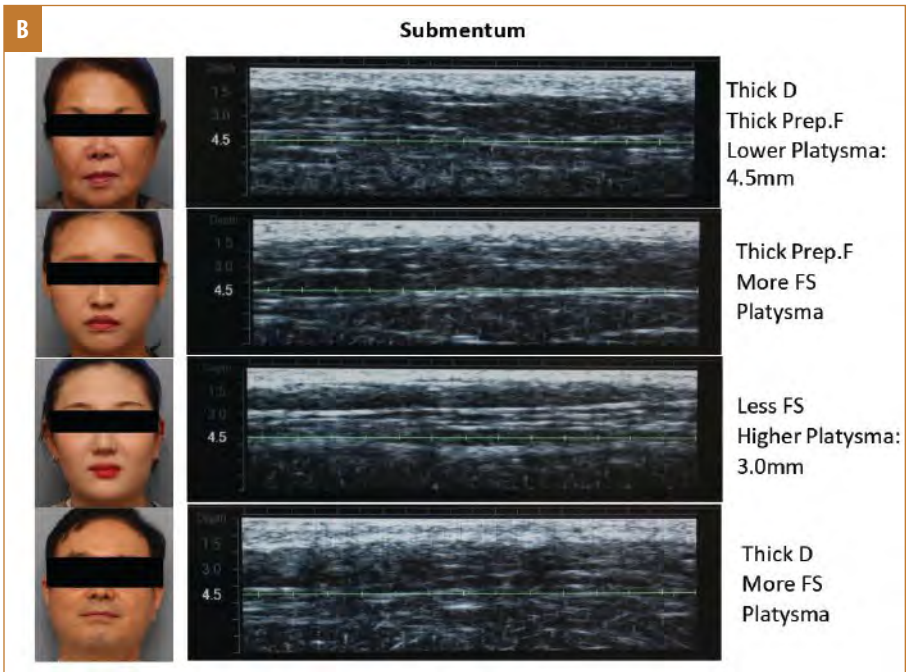

FIGURE 2B. Individual Variability in Asians; different Asian patients receiving MFU-V for A) eyebrow, B) submentum, and C) lower neck skin laxity display different subdermal anatomies. Age of patients, from top to bottom: 58 years, 34 years, 32 years, and 48 years.
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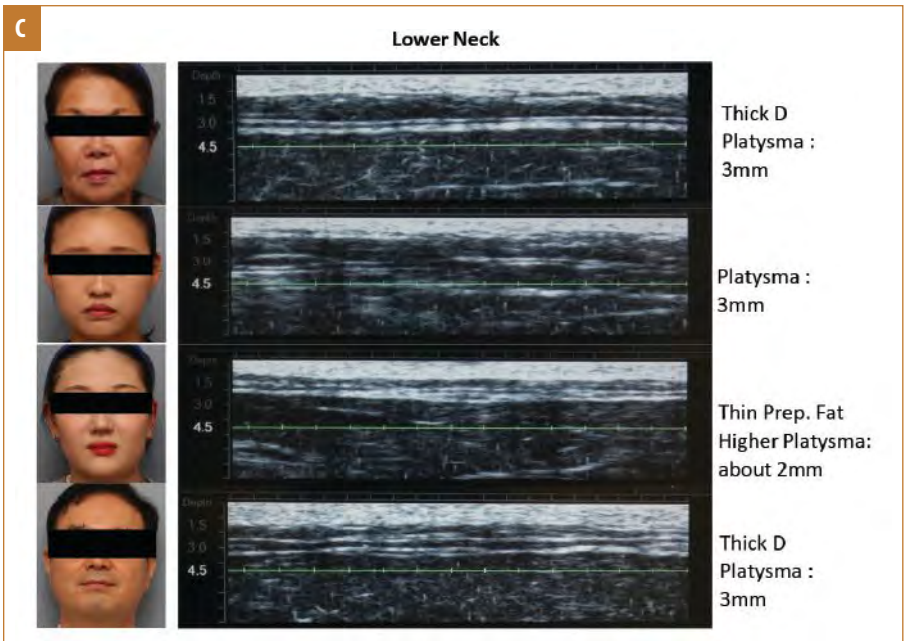

FIGURE 2C. Individual Variability in Asians; different Asian patients receiving MFU-V for A) eyebrow, B) submentum, and C) lower neck skin laxity display different subdermal anatomies. Age of patients, from top to bottom: 58 years, 34 years, 32 years, and 48 years.
FM: frontalis muscle; D: dermis; FS: fibrous septae; SM: skeletal muscle; S: subcutaneous fat; B: bone; V: vessel. Image courtesy of Dr. Je-Young Park. Informed and written patient consents were obtained for the use of patient images.

recommendations for patient selection, treatment planning, and customization when using MFU-V. The recommendations are summarized henceforth.

Treatment plans should be personalized for optimal outcomes. Target areas must be mapped, and patients must be selected correctly. Those unsuitable for MFU-V should be offered alternatives, such as surgery. Patient customizations should include demographic considerations, such as age, body mass index, the number of treatment lines, energy settings, and treatment depths;[43] the treatment strategy, as determined by the patient's goal(s) of restoration, prevention, or maintenance; and safety considerations. The individualized aging pathology should also be assessed before treatment. Ultrasound imaging should be performed to enable the correct selection of transducer depths and line numbers. Higher-density treatments (i.e., more lines per depth) lead to more ideal outcomes; older patients might need multiple treatments to achieve desired outcomes and more frequent treatments to maintain results. Although a treatment interval of 12 to 18 months is effective for maintenance,[43] this can be adjusted according to age. Younger patients (30–45 years) and those seeking early intervention or rejuvenation might require retreatment at longer intervals, such as every 24 months, while older patients (>50 years) might need treatments every 12 months. Physicians should tailor their strategies to each patient's age and clinical conditions.

Patient comfort must be well managed. MFU-V discomfort varies between patients and depends upon the area being treated.[5] As with all other energy-based procedures, no standard regimen for pain management exists. Nevertheless, transdermally-delivered lidocaine 4%/benzocaine 20% or compounded lidocaine 23%/teracaine 7% are effective at mitigating discomfort during MFU-V treatment.[78] With fewer treatment pauses (due to less patient discomfort), treatment efficacy is improved. All experts agreed that even when trying to achieve the required treatment density (or the number of lines of MFU), using a lower MFU energy level improves patient comfort and produces better outcomes than treatments performed at maximum energy levels, which risk patients dropping out midway. While pain and comfort management are essential to ensure treatment adherence, patient education is also necessary to ensure patient satisfaction. Moreover, a positive treatment experience increases the likelihood of patients returning for future treatments.

Visualization is important for safety. Clinicians must recognize when patients unknowingly encounter counterfeit aesthetic devices and injectables—for example, when they receive less expensive treatments—and be equipped to deal with such situations. Using counterfeit or copycat systems that image tissues incorrectly, or that do not image tissues at all, can damage nerves, blood vessels, and muscles, or cause burns that lead to permanent scarring, thus compromising patient safety.

THE FUTURE OF SKIN TIGHTENING

Aside from facial skin tightening and lifting, MFU also benefits lax skin on limbs, such as the knees, thighs, elbows, and upper arms, as well as the buttocks.[31–34] Using MFU-V alongside CaHA fillers on the buttocks and thighs, neocollagenesis was induced and found to improve skin laxity and the appearance of cellulite.[74] To assess its effects on the abdomen, one of our authors evaluated MFU-V for skin and soft tissue laxity in patients at six to 24 months postpartum.[79] Patients were treated in an area of the anterior abdominal wall between the umbilicus superiorly, the anterior superior iliac spines laterally, and the symphysis pubis inferiorly. Twenty patients received a total of 1,140 lines each, delivered using the 4-MHz/4.5-mm transducer to target Scarpa's fascia, the 7-MHz/3.0-mm transducer for Camper's fascia, and the 10-MHz/1.5-mm transducer on dermal and subdermal layers. In addition, one patient received 540 lines on the right hemi-abdomen six weeks before a previously planned abdominoplasty. The patient's left hemi-abdomen was maintained as a control for comparative histological analysis and intraoperative evaluation of tissue layers. Statistically significant improvements in lower abdominal wall laxity and excellent patient satisfaction were reported. Pretreated hemi-abdomen tissues exhibited neocollagenesis, fibrous septae thickening, and adipocyte sparing as compared with the untreated control hemi-abdomen. Seventeen patients experienced mild postprocedural pain, which resolved after four days with no significant adverse events. Thus, MFU-V was found to be safe and effective in improving abdominal skin laxity in postpartum patients and would suit other areas with well-defined superficial fascial systems.

Since its initial success at skin lifting and tightening in the brow in 2009, continued clinical development and study of MFU-V means that it is now poised for use in even more anatomical areas and indications. We envisage that its users will continue to drive innovations, including its combination with diluted CaHA, which can produce synergistic aesthetic effects and enhance neocollagenesis.

CONCLUSION

Unlike other platforms that claim similar technologies, efficacy, or safety, only MFU-V is backed by an extensive body of peer-reviewed, published scientific and clinical evidence, and only MFU-V has the patented DeepSEE® technology which allows users to noninvasively see through the skin. With this unparalleled ability to visualize specific tissue planes, clinicians can precisely deliver MFU energy for optimal lifting and tightening. Patient comfort and safety are enhanced as MFU-V causes less downtime and discomfort than traditional, face-lift surgeries and is therefore ideal for the many patients who now demand time-efficient, noninvasive, and durable solutions.

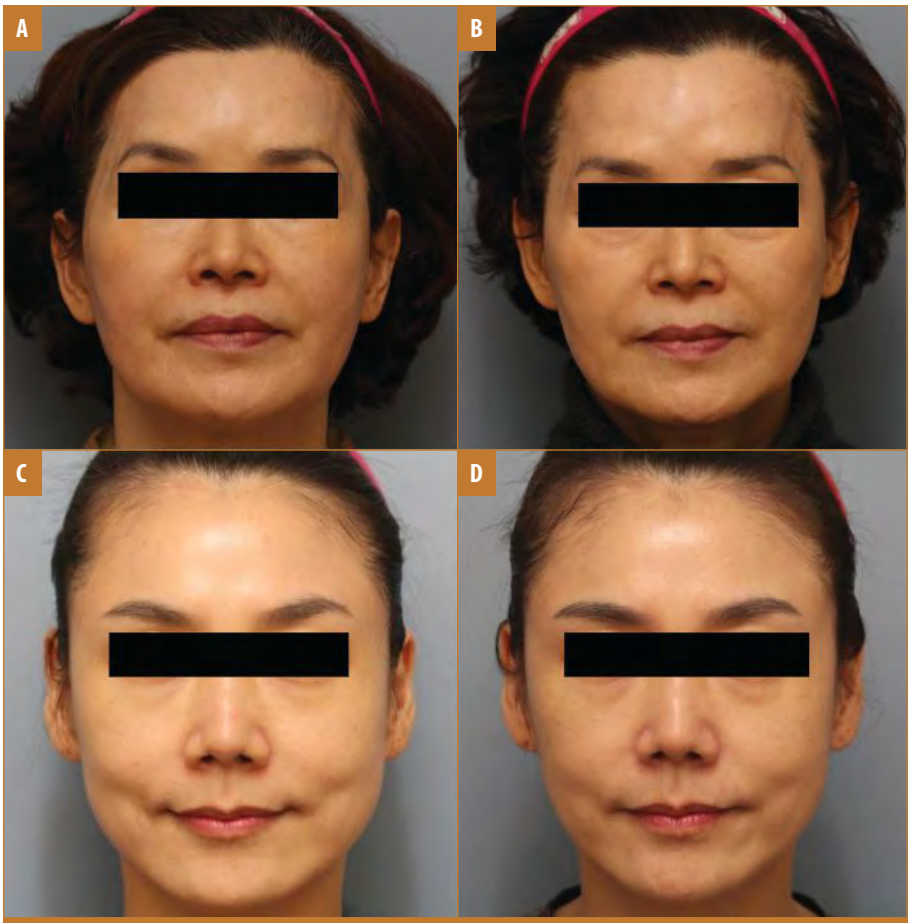

FIGURE 3. Adverse outcomes following high-intensity focused ultrasound (HIFU) in two patients; A, C) Patients before HIFU; B, D) Patients after HIFU
Images courtesy of Dr. Je-Young Park; informed and written patient consent was obtained for the use of patient images.

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